K061466

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
(21 CFR 807.92) [21 CFR 807.87(H)]

DEC - 4 2006

INTIMOL™ Liquid Personal Lubricant

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.87(h), this information serves as a Summary of Safety and Effectiveness for the **INTIMOL™ Liquid Personal Lubricant**

Submitted By: DLC Laboratories, Inc.
7008 Marcelle Street
Paramount, CA 90723

Date: May 23, 2006

Contact Person: Juan Manzur
Operations Manager
Telephone: 562-602-2184 or 800-858-3889
Fax: 562-602-1931

Proprietary Name: INTIMOL™

Common Name: Personal Lubricant

Classification Name: The General Hospital and Personal Use Device section of the General Medical Devices Panel within the FDA's Center for Medical Device & Radiological Health considers patient lubricants (21 CFR §880.6375, Class I devices) to be **Class II** devices when promoted as being compatible for use with condoms (21 CFR §884.5300)

Predicate Device: Wet® Light Personal Moisturizer (K013086)
Astroglide® Personal Lubricant (K935299)
K-Y® Liquid Personal Lubricant (K955648)

Intended Use: INTIMOL™ Liquid Personal lubricant is principally intended as personal lubricant to supplement the body's natural lubricating fluids, and to enhance the ease and comfort of intimate sexual activity with or without a latex condom.

Device Description
INTIMOL™ is a non-sterile, aqueous-based personal lubricant designed to supplement the body's own natural lubrication fluids. It is specifically formulated to be a clear, non-irritating, non-greasy, non-staining, gel-like liquid and is compatible

for use with or without a latex condom during intimate sexual activity as evidenced by condom compatibility test results. This device is not a contraceptive or spermicide, nor does it contain any such component.
The product is packaged in a plastic bottle with a flip-top cap.

Summary of Technological Characteristics
INTIMOL™ Liquid Personal lubricant contains ingredients that are substantially the same as those used in the manufacture of the predicate devices. The ingredients meet specifications defined in the United State Pharmacopoeia (USP) or National Formulary (NF), and are "generally recognized as safe for their intended use" (21 CFR 172.515).

Summary of Substantial Equivalence Information:
The intended use, ingredients, and application of the proposed device are substantially equivalent to those of the predicate devices. In determining substantial equivalence, the INTIMOL™ has been compared with the following legally marketed device to which the Sponsor claims substantial equivalence.

The table below compares the technological characteristics of INTIMOL™ Liquid Personal Lubricant to the predicate devices, Wet® Light Personal Moisturizer, K-Y® Liquid Personal Lubricant and Astroglide®.

Feature	Intimol™ Personal Lubricant	Wet Light Personal Moisturizer	K-Y® Personal Lubricant	Astroglide®
Manufacturer	DLC Laboratories, Inc.	Trigg Laboratories, Inc.	McNeil-PPC, Inc.	BioFilm Inc.
Contains purified water	Yes	Yes	Yes	Yes
Contains glycerin	Yes	Yes	Yes	Yes
Contains Cellulose thickeners	Yes	Yes	Yes	No
Contains Methylparaben	Yes	Yes	Yes	Yes
Contains Propylparaben	Yes	No	No	Yes
Contains Propylene glycol	Yes	Yes	Yes	Yes
Contains Aloe Vera	Yes	Yes	No	No
Over-the-Counter Use	Yes	Yes	Yes	Yes
Labeled water soluble	Yes	Yes	Yes	Yes
Labeled non-staining	Yes	Yes	Yes	Yes
Labeled condom compatible	Yes	Yes	Yes	Yes
Contains alcohol and fragrance	No	No	No	No
Container material	Plastic	Plastic	Plastic	Plastic
Sterile	No	No	No	No

The product was tested by independent laboratories for condom compatibility, biocompatibility and preservative effectiveness. Final results from these tests demonstrate that the device meets established acceptance criteria in accordance with the identified industry standards.

Conclusion

INTIMOL™ Liquid Personal Lubricant is substantially equivalent to its predicate devices, Wet® Light Personal Moisturizer, K-Y® Liquid Personal Lubricant and Astroglide®. All of these products have the same intended use and similar technological characteristics. Therefore, no new safety and effectiveness issues are expected to be raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Juan Manzur
Operations Manager
DLC Laboratories, Inc.
7008 Marcelle Street
PARAMOUNT CA 90723

DEC - 4 2006

Re: K061466
Trade/Device Name: INTIMOL™ Liquid Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: November 16, 2006
Received: November 20, 2006

Dear Mr. Manzur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

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510(k) Number (if known): K061466

Device Name: **INTIMOL™ Liquid Personal Lubricant**

Indications for Use:
INTIMOL™ Liquid Personal lubricant is principally intended as personal lubricant to supplement the body's natural lubricating fluids, and to enhance the ease and comfort of intimate sexual activity with or without a latex condom.

Prescription Use _____ ~~AND~~/OR Over-The Counter Use ___X___
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061466